

REMARKS

In the Office Action dated March 11, 2011, claims 3-6, 9, 10, 12, 13 and 15-23 were rejected under 35 U.S.C. § 112, first paragraph. Claims 3-6, 9, 10, 12, 13, 15-24, 28 and 30-33 were rejected under 35 U.S.C. § 112, second paragraph. Claims 3-6, 12, 13, 15-19 and 21-23 were rejected under 35 U.S.C. § 103 as being unpatentable over Houston et al. (U.S. Patent Publication No. 2002/0179166) (Houston), in view of Evans et al. (U.S. Patent No. 5,709,713) (Evans), and in view of Edwin et al. (U.S. Patent No. 6,053,943) (Edwin). Claims 9 and 10 were rejected as being unpatentable over Houston, Evans and Edwin in further view of Inderbitzen et al. (U.S. Patent No. 5,484,411) (Inderbitzen). Claim 20 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Houston, Evans and Edwin in further view of Igaki et al. (U.S. Patent No. 5,733,327) (Igaki). Claims 24 and 28 were rejected as being unpatentable over Houston and Evans in view of Cymbalisty (U.S. Patent No. 6,896,007). Finally, claims 30-33 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Houston.

35 U.S.C. § 112, First Paragraph

It was stated that claims 3-6, 9, 10, 12, 13 and 15-23 were rejected under 35 U.S.C. § 112, first paragraph as failing to comply with the written description requirement. In reply, applicants note the embodiment of Figures 1-3 and the corresponding description on page 17, at lines 24-34. It is there explained that one effect of the helical portion 6 is to create a cross sectional shape approximating to a circle with a segment removed in the region corresponding to the helical portion. Figure 3 is identified. It is further explained that a helical center line 40 (Fig. 1) is defined by the locus of centroids 9 along the length of the stent. Clearly, the center line has a pitch. The length of the pitch is defined by the distance in the longitudinal direction for the centroid 9 to rotate from a starting position through 360° back to such starting position. This pitch has to be exactly the same as that of the helical portion which creates the cross sectional shape approximating to a circle with a segment removed. Therefore, the pitch of the helical center line of the flow lumen and the pitch of the helical portion are the same. Thus, no new subject matter is being disclosed by this feature of claim 12.

Moreover, applicants note Figure 8 of the instant application where the helical center line 40 is shown extending over one pitch. The pitch of the helical portion in this drawing can be seen to be approximately the same as that of the center line. Although this drawing shows an experimental balloon, it is stated in the instant specification (page 22, lines 23-25) that the shape of the expanded experimental balloon membranes may be considered as analogous to that of an expanded stent outer wall.

In both cases, it is clear that the helical portion on the wall of the stent causes the stent to adopt a helical center line. Inevitably, the pitch of the helical portion and that of the helical center line are the same. Indeed, they could not be different.

In sum, the feature of substantially equal pitches does not constitute new matter and the applicants clearly had possession of the subject matter recited in claim 12 at the time that the instant application was filed.

35 U.S.C. § 112, Second Paragraph Rejection

It was stated in the Office Action that claims 3-6, 9, 10, 12, 13, 15-24, 28 and 30-33 were indefinite for failing to particularly point out and distinctly claim the subject matter. In essence, as to independent claim 12, it was stated that the transitional phrase is in line 9 and makes unclear what limitations are being positively recited. As to independent claims 24 and 30, it was asserted that the transitional phrase is missing altogether, making it unclear what limitations are being positively recited.

In response, applicant has changed the location of the transitional phrase in claim 12. Moreover, applicants have added a transitional phrase to both claims 24 and 30. Therefore, it is respectfully submitted that this rejection is now moot.

Independent Claim 12 and Dependent Claims 3-6, 9, 10, 13 and 15-23

It was stated in the Office Action that the subject matter of claim 12 is obvious over a combination of Houston, Evans and Edwin. In the rejection set forth on pages 4 and 5 of the Office Action, it is admitted that the feature that the helical center line of the flow lumen and the helical portion have substantially equal pitches is not addressed. Since the § 112, first paragraph rejection against this limitation has been overcome, this

feature should also be considered to distinguish over the asserted three way combination.

Moreover, Houston and Evans do not disclose a helical portion which resists extension more than portions of the stent adjacent to the helical portion. Edwin is said to disclose such a structure. Edwin discloses a cylindrical graft having a helical "support structure" 26 wound around the outside. The support structure comprises a wire-like member 28 covered by coextruded beading 24 and having a plurality of strain relief sections 30 along its length. The strain relief sections are regions where the beading is not present and are therefore weaker than the regions where the beading is present, such that the strain relief sections can deform to accommodate longitudinal or radial expansion. The expansion of the graft can therefore be controlled by the strain relief sections (see column 7, line 48 to column 8, line 21, as well as column 4, lines 9-29). Apparently, the strain relief sections are considered to provide a helical portion which resists extension more than the adjacent portions, since they will have "a degree of resistance to expansion" (see page 5 of the Office Action).

In the stent recited in claim 12, the helical portion of lower extensibility creates the helical shape of the stent so that the pitch of the helical portion is the same as the pitch of the helical center line of the stent when the stent is expanded. In contrast, the helical portion of Edwin is merely a support portion and has nothing whatsoever to do with the shape of the graft on which it is wound. If the helical portion of Edwin was applied to the stent of Houston, it would only be for support purposes and the skilled person in the art would have no reason whatsoever to provide the stent and helical portion with equal pitches. The pitch of the helical portion of Edwin is much less than the diameter of the graft while the pitch of the curvature of the relevant embodiment of Houston (i.e., Figure 5) is much larger than the diameter of the stent. Thus, if Edwin were applied to Houston, the result would be a helical winding around Houston with a pitch much smaller than the diameter of Houston. There would certainly be no reason for the person of ordinary skill in the art to choose the pitch of the helical winding to be the same as the pitch of the helical flow lumen. This feature is entirely absent from even the asserted three way combination.

Moreover, applicants note that attempting to combine the helical portion of Edwin with the stent of Houston would create great technical difficulties relating to i) crimping and ii) long term integrity. Ties or fixings of some sort would appear to be necessary to attach the Edwin helical support to the stent of Figure 5 in Houston. But, such ties or fixings would obstruct or retard the wire mesh of the stent from collapsing effectively during crimping. In addition, there would be fretting and wear concerns if the beading is made of PTFE as taught in Edwin because such beading is moving relative to the stent surface.

As a result, it is respectfully submitted that independent claim 12 patentably defines, not only over the asserted three-way combination of Houston, Evans and Edwin, but also over the remainder of the cited art.

Dependent claims 3-6, 13, 15-19 and 21-23 merely further patentably define the detailed subject matter of their parent claim or each other. As such, these claims are also believed to be in condition for allowance over the art of record.

Claims 9 and 10 were rejected over Houston, Evans and Edwin in further view of Inderbitzen. However, Inderbitzen does not provide those teachings which are clearly absent from the asserted three way combination mentioned above. As a result, claims 9 and 10 also patentably define over the four way combination mentioned herein.

Dependent claim 20 was rejected over Houston, Evans and Edwin in further view of Igaki. But, Igaki does not provide those teachings which are clearly absent from the asserted three way combination mentioned herein. Therefore, claim 20 is also in condition for allowance over the four way combination, as well as the remainder of the cited art.

Independent Claim 24 and Dependent Claim 28

Claims 24 and 28 were rejected as being unpatentable over the combination of Houston, Evans and Cymbalistry.

In the Office Action, the applicants' attention was directed to Cymbalistry at column 3, lines 28-46. The most relevant part of this reads as follows:

"In accordance with the present invention, the undulations may take a variety of serpentine paths or shapes with different pitches (FIG. 3) repetitive or varying waves and differing cross sections, FIGS. 4, 4a, 5, 7."

In other words, there is a disclosure that the "waves" of Cymbalisty's undulations may vary.

However, this disclosure does not provide sufficient teaching for a skilled person in the art to modify the Houston stent so as to have an upstream end which introduces a swirl flow effect together with a variation in the helix angle and/or amplitude of the helical center line so as to increase the swirl flow effect in the downstream direction from that end. In fact, it could just as easily decrease the swirl flow effect in the downstream direction. A mere reference to a varying undulation does not provide a teaching which would prompt a skilled person designing a stent to adopt the structure recited in claim 24 so as to increase the swirl flow effect in a downstream direction.

There is no disclosure in Cymbalisty about imparting a relatively gentle swirl flow at an upstream end of the pipe followed by an increased swirl generating effect. In fact, a "varying" undulation could mean a large wave at the entry to the pipe in order to establish mixing and then a smaller wave further downstream. This design would be consistent with Cymbalisty's aim of seeking a mixing of the oil sands slurry (column 3, lines 12-14) and turbulence to keep the solids suspended (column 3, line 66 to column 4, line 3). Thus, Cymbalisty teaches away from the concept of a relatively restrained or introductory swirl flow effect because of the potential disadvantage of inadequate mixing leading to a depositing of solids along the base of the pipe (see column 4, lines 1-2) in the introductory region.

Furthermore, Cymbalisty teaches a conduit used for processing mixtures of oil sands and teaches mixing and transporting abrasive materials which is irrelevant to the stent recited in claim 24. Also, the conduit in Cymbalisty is designed to promote a flow of a fluid with a high concentration of solids (above 70 percent) which is not true of fluid conduits in a human or animal body. Further, Cymbalisty deals with pipe diameters greater than 10 inches and rigid pipes, not the stents recited in claim 24. Thus, it is in a greatly different field of endeavor from that of prosthetic medical devices, such as stents which are meant to be inserted in a fluid conduit of a human or animal body.

As a result, it is respectfully submitted that independent claim 24 patentably defines over the asserted three way combination, as well as the remainder of the cited art.

Dependent claim 28 merely further patentably defines the detailed subject matter of claim 24. As such, this claim is also believed to be in condition for allowance over the three way combination, as well as the remainder of the cited art.

Independent Claim 30 and Dependent Claims 31-33

Claims 30-33 were rejected as being unpatentable over Houston. It was asserted that Houston discloses a stent including an outer wall formed of a mesh structure or a plurality of strands that is capable of being collapsed and expanded and is capable of following a substantially helical center line. Figure 5 of Houston is identified. Applicants note that claim 30 recites a stent which comprises an outer wall for engagement with an associated fluid conduit, wherein the outer wall in the expanded condition follows a substantially helical path so as to promote a swirl flow effect within the associated conduit and wherein the stent in the expanded condition is substantially free of ribs which would project into the flow lumen of the conduit. No new subject matter is being recited by the addition to claim 30 of the phrase "wherein the stent, in the expanded condition is substantially free of ribs which would project into the flow lumen of the conduit." Rather, that subject matter is already found in pending claim 24.

In contrast, in Houston, the reason there is a swirling flow is because there are ribs or protrusions extending into the flow path (4a-4c in Figure 2, 13a-13c in Figure 7B, 19 in Figure 8B, and 24 in Figures 9A and 9B). These project into the flow lumen and interfere with flow. In contrast, the stent recited in claim 30 is, in its expanded condition, substantially free of ribs which would project into the flow lumen of the conduit.

Therefore, claim 30 patentably defines over Houston, as well as the remainder of the cited art. Claims 31-33 merely further patentably define the detailed subject matter of their parent claim or each other. As such, these claims are also believed to be in condition for allowance over the art of record.

In view of the foregoing, it is respectfully submitted that all of the pending claims are now in condition for allowance. Such allowance is earnestly solicited.

Respectfully submitted,

FAY SHARPE LLP

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Date

A handwritten signature in cursive script, reading "Jay F. Moldovanyi", is written over a horizontal line.

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